

BfArM Prepares for the Future

Susanne Keitel and *Reinhard Kurth* explain how the reorganisation of licensing activities at Germany's BfArM will allow it to play a greater role in EU regulatory procedures.

The organisation and procedures of BfArM, Germany's federal institute for drugs and medical devices, have been restructured and streamlined following an evaluation of the agency's performance. This was in response to frequent complaints by the pharmaceutical industry concerning the time taken by BfArM to process applications for national marketing authorisations. Those involved in the evaluation included BfArM staff, representatives of industry, members of the then federal ministry of health (BMG), sister agencies (such as the Paul-Ehrlich Institute, the German competent authority for blood products and vaccines, and DIMDI, the German institute of medical documentation and information) and a group of external consultants.

As of 1 July 2005, BfArM implemented the reorganisation of its licensing divisions with an emphasis on strengthening drug safety and preventive health protection while simultaneously accelerating the processing of applications for marketing authorisation. The aim of the reorganisation has been to ensure that the service and communication needs of the pharmaceutical industry in the context of global competition and a continually changing environment are met, while strengthening cooperation within the network of European regulatory agencies. The reorganisation has been an integral step in the transformation of BfArM into a competitive and autonomous scientific agency with a modern style of management. The reorganisation has focused specifically on establishing the following:

- a flexible management system which meets international standards and enables rapid high-quality decision-making;
- less hierarchical and more efficient structures within which competence and responsibility are clearly assigned;
- a high degree of scientific competence for assessors;
- stronger identification of staff with their projects by introducing an interdisciplinary structure within the licensing divisions; and
- continuous and sustained change-management system, including regular benchmarking of all aspects of the agency.

The new structure

The licensing section now consists of one division for validation and simplified procedures (licensing division 1), three scientific divisions for chemically defined substances (licensing divisions 2 to 4) and one scientific division specialising in medicinal products in the areas of complementary and alternative medicine, eg, herbal medicinal products, homoeopathics and anthroposophics (licensing division 5).

All applications, variations and renewals, regardless of the respective procedure (ie, national or European), are first validated by division 1 before being distributed to the scientific division dealing with that particular type of product. Procedures that do not require an in-depth scientific assessment, ie, simplified procedures such as parallel imports and Type IA variations, are entirely handled and finalised by division 1, allowing the scientific divisions to concentrate on the more complex applications.

A specialised group of project managers controls the different procedures within each scientific licensing division to ensure that the process is completed as quickly as possible. Applications are evaluated, according to their assigned ATC medicine classification codes, by project teams of scientists representing preclinical, clinical and quality assessment. The scientific interchange between toxicologists, clinicians and pharmacists is therefore enhanced and the assessment is based on a holistic approach.

Using parallel assessment for all types of procedures, loops in the evaluation process (ie, time spent on transferring applications among various units) are minimised and overall processing times are significantly shortened. Project managers within the respective licensing divisions are able at any time to answer questions from applicants regarding the status of their applications.

As scientists are responsible for each different type of pre- and post-approval procedure for comparable medicinal products that require scientific assessment – such as national and European applications, variations and renewals – equal standards and consistency in the decision making

Complaints about time taken to process marketing authorisation applications precipitated the restructuring

The reorganisation was aimed at producing a more flexible management system and a less hierarchical structure

All applications, variations and renewals are first validated by division 1 before being distributed to the relevant scientific division

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Training of assessors and peer review of all important applications has been formalised

process are ensured. In addition, training of assessors and peer review of all important applications, for example applications under the mutual recognition, decentralised or centralised procedures, where BfArM acts as the reference member state or (co-)rapporteur, has been formalised.

Additional support in a range of different areas is provided by division 6, "scientific services". The responsibilities of this division include providing scientific advice, a service much appreciated by the pharmaceutical industry and which will be further promoted. This will be done by "advertising" the scientific advice service in meetings with industry and by actively approaching companies. Division 6 also deals with the assessment of clinical trial applications, another area where BfArM has already received recognition for meeting industry's expectations.

BfArM's contribution to the EU network

A new "EU and International Affairs" unit has been established to increase the representation of BfArM's opinion in EU committees

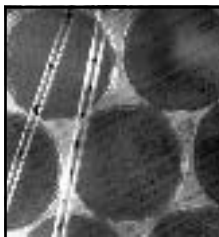
BfArM is strengthening its visibility within the EU and at the international level. A new organisational unit, "EU and International Affairs", has been established to focus on improving the representation of BfArM's opinion in the different scientific and procedural EU committees and working parties, as well as on optimising the flow of information regarding developments within the EU regulatory system of relevance to BfArM staff. One of its priority areas is to improve its performance in the centralised procedure by making high-quality scientific and regulatory contributions in those areas most relevant to industry.

It also intends to act more frequently as a reference member state in the decentralised and mutual recognition procedures. In order to optimise the scientific and regulatory resources for these procedures, BfArM is now focusing on improving dialogue and communication with the pharmaceutical industry through informal discussions on the development portfolios of companies interested in closer cooperation with the agency.

The future

Adhering to timelines for all future applications is the new BfArM's top priority

With the successful implementation of the new structure, and having finalised the assessment of its "legacy products" (those that were on the market before new EU pharmaceutical legislation came into effect in the mid-1970s) in December 2005, BfArM is now focusing on the processing of pending national applications. Adhering to timelines for all future applications is the new BfArM's top priority.



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